REMARKS

Personal Interview with Examiner

Applicants gratefully acknowledge the courtesies extended during the personal interview conducted with Examiner D. L. Jones on August 5, 2008, the substance of which is reflected below.

Specification

The specification is amended to insert a "Brief Description of the Drawings" as required by the Examiner.

Obviousness-Type Double Patenting

The Office Action presents a series of obviousness-type double patenting rejections including rejections over the claims of US patent no. 6,558,701 and provisional rejections over the following US applications: Serial no. 10/837,755; Serial no. 10/665,552; Serial no. 10/016,130; and Serial no. 10/084,676.

As discussed during the interview, the claimed invention is directed to dosage formulations having the **same active substance** present in **at least two different salt forms.** The response to the election of species identified the active substance as tramadol. Thus, for the species elected for initial examination, the formulation has **tramadol present in at least two different salt forms.** The obvious-type double patenting rejections all appear to not take into consideration this aspect of the claims. Instead, the Office Action appears to characterize the invention as being directed to a combination of tramadol and diclofenac.

None of the references cited in the obviousness-type double patenting rejections teach or suggest a formulation as contemplated by the present claims.

US 6,558,701 is directed to a tablet having a tramadol layer and a diclofenac layer. Similarly, the applications having serial nos. 10/665,552 and 10/016,130 are directed to formulations containing tramadol and diclofenac in separate subunits.

The applications having serial nos. 10/837,755 and 10/084,676 are directed to formulations of tramadol, where the tramadol is present as a compound of tramadol and another acidic substance.

There is no disclosure in any of these documents of a formulation where a single active ingredient is present in the form of two different salts. Considering the elected species, where the active ingredient is tramadol, none of these documents teaches the skilled artisan to provide a single oral dosage formulation of tramadol in two different salt forms. Accordingly, the cited patent and applications do not render obvious the present claims and these rejections cannot be properly maintained. For these reasons, reconsideration and withdrawal of these obviousness-type double patenting rejections are respectfully requested.

Written Description

The rejection of claim 5 under 35 U.S.C. § 112, first paragraph, for supposed lack of written description, is respectfully traversed.

This rejection is directed to the breadth of claim 5, insofar as claim 5 recites a number of possibilities for a suitable active ingredient. Like the obviousness rejections discussed above, this rejection reflects a lack of appreciation for the present invention. In accordance with the presently claimed invention, controlled release of an active substance is achieved without using additional measures, such as a coating or matrix. In particular, the claimed invention allows for controlled release through the elegant technique of providing two or more different salts of the same active ingredient. Because the two different salt forms of the active ingredient are selected so that they have different water solubilities, the active substance is released at different rates than it would be, if, for instance the active substance were present in the form of a single salt.

This inventive principle has broad ranging applicability to a variety of active ingredients and should not be limited to any particular examples of active ingredients. Thus, the claim is commensurate with the scope of the invention achieved by the present applicants. In contrast, the Office Action appears to

suggest that the patent applicants should not be entitled to protection commensurate with the scope of their invention. In particular, page 7 offers a final conclusory assertion that while claim 5 recites broad groups, the specification does not describe specific active ingredients. However, the law is clear that a patent applicant need not describe that which is already known. Indeed the classes of active ingredients recited in claim 5 are all well known so that various active ingredients would be immediately known and envisioned by the highly skilled and well educated person commonly working in this art. Based on this knowledge, there is no need for the specification to list each and every single member of the classes of active ingredients recited in claim 5.

This claim does not present an instance of an applicant claiming a structure, for instance of a compound, which they did not know. Instead, the groups of active ingredients are all well known, and the law does not burden a patent applicant with reciting that which is already known in the art. Indeed if it were the case that an applicant did have to present that which is already known, the patent specifications would go on and on without, so as to attempt to meet this heightened standard for the written description requirement. Fortunately for all concerned, the law does not present such a heightened standard for written description and it is well settled that a patent applicant need not describe that which is already known. "What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail...If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met." (MPEP §2163 – citations omitted).

Because the function of the invention is directed to the property of providing a single active ingredient in at least two different salt forms where those forms have differing solubilities, the features of the invention can be achieved regardless of the particular active ingredient selected. For this reason, it is entirely appropriate for the US Patent and Trademark Office to allow claim 5 in its present form. Moreover, for claim 5, the written description requirement

is necessarily met because this is an original claim and it is supported in near verbatim language in the specification. Accordingly, there can be no question that the present applicants contemplated the full scope of this claim as part of their invention.

The MPEP explains that the USPTO must establish a prima facie case when making a written description rejection. (MPEP §§ 706.07, 2163 (III)(A)). To do so, the USPTO must present "a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims." (MPEP § 2163(III)(A)). Conclusory statements are insufficient to establish this evidence. Rather, every written description rejection "should be stated with a full development of the reasons...." (MPEP § 706.03). Applicants respectfully submit that the USPTO has not met its burden of showing that claim 5 is not adequately supported by the present specification.

Where, as here, the claim at issue is an originally-presented claim, "There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed." *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976)" (MPEP § 2163).

In view of the foregoing, reconsideration and withdrawal of the written description rejection are respectfully requested. Should the Examiner determine to maintain this rejection, the Examiner is respectfully requested to identify with particularity what words in the claim are deemed to not be adequately supported by the specification.

Definiteness

The rejection of claim 5 under 35 U.S.C. § 112, second paragraph, for supposed lack of definiteness, is respectfully traversed.

In this rejection the Office Action asserts that because the claim language is broad it is indefinite. However, the test for definiteness has never depended on whether or not the claim language is broad. In the present instance, the skilled artisan can readily ascertain whether or not a given formulation would

fall within the scope of the claim. Accordingly, the claim adequately provides for a clear and definite scope. There is nothing about the various groups of active ingredients that are listed in the claim that would present the skilled artisan with uncertainty. To the contrary, each of the proposed groups of active ingredients are known to the well educated and highly skilled person working in this technology. Indeed, the skilled artisan would know which active substances are embraced by the terms appearing in claim 5, each of which can be found in any standard medical dictionary.

Given that the inventive concept has applicability to a broad range of active ingredients, it would be unjust and improper to limit the applicants to solely certain exemplary compounds. The law relating to definiteness does not prevent an applicant from identifying a group of compounds by class rather than enumerating every single member of that class.

In view of the foregoing, reconsideration and withdrawal of the indefiniteness rejection are respectfully requested.

Obviousness

The rejection of claims 1, 3-9, 11, 12, 15, 17-19, 21, 30-32, 55-58 and 62-65 under 35 USC §103 as obvious over the combined disclosures of Krishnamurthy, U.S. 5,811,126; Gruber, U.S. 6,709,678 and Oshlack, WO 99/01111 is respectfully traversed.

As indicated above, the claimed invention is directed to dosage formulations having the **same active substance** present in **at least two different salt forms**. The response to the election of species identified the active substance as tramadol. Thus, for the species elected for initial examination, the formulation has **tramadol present in at least two different salt forms**. Like the obvious-type double patenting rejections discussed above, the obviousness rejection does not appear to not take into consideration this aspect of the claims. Instead, the Office Action appears to characterize the invention as being directed to a combination of tramadol and diclofenac.

None of the references cited in the obviousness rejection teach or suggest a formulation as contemplated by the present claims. Indeed, there does not appear to be anything in these references that teach a formulation as is presently claimed, where a single active ingredient is provided in at least two different salt forms.

Response to Comments

The Examiner's comment regarding the spelling of diclofenac is misplaced. The term "diclofenacate" refers to a salt made with diclofenac and is entirely proper to designate such a salt by the term diclofenacate. Accordingly, the language in the specification is correct and it is not necessary to amend the specification to recite diclofenac instead of diclofenacate.

Conclusion

For the foregoing reasons, the application is respectfully submitted to be in condition for allowance, and prompt, favorable action thereon is earnestly solicited.

Moreover, in view of the fact that withdrawn claims 10, 13, 14, 16, 19, 20, 22-29, 33-54 and 59-61 all depend from and are linked by allowable claim 1, rejoinder and allowance of these claims are also respectfully requested.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned at (202) 624-2845 would be appreciated since this should expedite the examination of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket No. 029310.50986).

Respectfully submitted,

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